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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation	12 VAC 30, Chapter 50
Regulation title	Drugs or drug categories which are not covered
Action title	Discontinue Coverage of Erectile Dysfunction Drugs for Sex Offenders
Document preparation date	

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Preamble

The APA (Section 2.2-4011) states that an “emergency situation” is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

- 1) Please explain why this is an “emergency situation” as described above.
- 2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The Administrative Process Act (Section 2.2-4011) states that an “emergency situation” is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation

shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. This suggested emergency regulation meets the standard at COV 2.2-4011(i) as discussed below.

Virginia has become aware that there is a segment of the Medicaid population that are convicted sex offenders that may have access to Medicaid coverage of drugs used to treat erectile dysfunction. The Governor has determined that the use of such drugs by convicted sex offenders constitutes an imminent threat to the health or safety of the citizens of the Commonwealth.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Drugs or Drug Categories Which Are Not Covered: Discontinue Coverage of Erectile Dysfunction Drugs for Sex Offenders (12 VAC 30-5-520) and also authorize the initiation of the promulgation process provided for in § 2.2-4007.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of this regulatory action is to halt Medicaid reimbursement for erectile dysfunction drugs for convicted sex offenders. This action is accomplished by adding to the list of non-covered drugs described in 12 VAC 30-50-520 erectile dysfunction drugs for convicted sex offenders.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The *Code of Virginia* (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The *Code of Virginia* (1950) as amended, § 32.1-324, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

The section of the State Plan for Medical Assistance that is affected by this change is the Amount, Duration and Scope of Services: Drugs or drug categories which are not covered [(Attachment 3.1-A & B, Supplement 5 (12VAC30-50-520)].

This regulation is being promulgated to address the health and safety issues presented by Medicaid coverage of erectile dysfunction drugs for convicted sex offenders. In addition to concern for the citizens of the Commonwealth, DMAS has received direction from the federal Medicaid authority concerning the coverage of erectile dysfunction drug for sex offenders. In a May 23, 2005 letter to State Medicaid Directors, the Centers for Medicare and Medicaid Services (CMS) advised states that “the use of these drugs in the case of a sex offender is not appropriate and Medicaid should not pay for the cost of such drugs in such circumstances.” The letter further advised that CMS would no longer provide federal financial participation for erectile dysfunction drugs dispensed to convicted sex offenders.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 30-50-520		No limit for erectile dysfunction drugs	Limits reimbursement for erectile dysfunction drugs for convicted sex offenders

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

The Agency considered accomplishing this limitation through its Drug Utilization Review (DUR) program, however it was determined that the scope of the DUR program, being limited to clinical or medical decisions, was not the appropriate vehicle to effect this policy change.

Family impact

Please assess the impact of the emergency regulatory action on the institution of the family and family stability.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; or encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It does not strengthen or erode the marital commitment, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.